

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

IN RE NATIONAL	:	CIVIL ACTION NO.
PRESCRIPTION OPIATE	:	3:17-01362
LITIGATION	:	
Cabell County Commission	:	and
and City of Huntington, WV	:	
	:	CIVIL ACTION NO.
	:	3:17-01665

EXPERT REPORT OF CRAIG J. MCCANN, PH.D., CFA

August 3, 2020

19. In Section VIII, I describe certain charts and tables that are attached to this report. In Section IX, I summarize my conclusions.

20. I continue to review documents and gather information and reserve the right to update my analysis and opinions based upon that further review of documents and based on any new information including, possibly, reports of other experts I may receive.

V. National ARCOS Data

21. ARCOS is the system through which manufacturers and distributors report transactions of controlled substances to the DEA.⁴ ARCOS Data covers all fifty states, the District of Columbia, Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands, Armed Forces-Americas, Armed Forces-EMEA, Armed Forces-Pacific, and Palau.

A. Receipt of ARCOS Data from the DEA

22. In the multi-district litigation, the DEA produced a set of ARCOS Data reflecting transactions in drug products containing one or more of fourteen drugs: buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, powdered opium, oxycodone, oxymorphone, and tapentadol from January 1, 2006 through December 31, 2014.

23. On or about April 20, 2018, the DEA produced ARCOS Data reflecting transactions in oxycodone, hydrocodone, hydromorphone, and fentanyl for six states: Alabama, Florida, Illinois, Michigan, Ohio, and West

⁴ www.deadiversion.usdoj.gov/arcos/index.html, accessed on 29 November 2018.

Virginia. On or about May 20, 2018, the DEA produced transaction data for these four drugs for the remaining states. The May 20, 2018 production was missing pharmacy names and had some duplicate transactions and obvious errors. At my request, the DEA reproduced the May 20, 2018 data with pharmacy names and errors in the May 20, 2018 production largely corrected on or about June 5, 2018.

24. Additionally, the DEA produced ARCOS Data for all states for oxymorphone, tapentadol, buprenorphine, and morphine on or about July 6, 2018; for codeine, dihydrocodeine, meperidine, and powdered opium on or about July 24, 2018; and for methadone and levorphanol on or about August 28, 2018. The timing and amount of ARCOS Data produced by the DEA are summarized in Table 1. In total, the ARCOS Data has 500,709,803 transaction records – 444,819,182 transaction records involving Dispensers.

Table 1 ARCOS Opioid Transaction Data Produced by DEA

			Transactions with Dispensers				
	Drug	# of All	# of		Dosage	Calculated Base	Calculated
Drug Name	Code	Transactions	Transactions	Dosage Units	Units %	Weight	Weight %
Received June 5, 2018							
Hydrocodone	9193	189,611,242	174,829,777	74,285,510,348	53.04%	436,729,519	25.85%
Oxycodone	9143	116,411,941	106,210,465	39,978,942,635	28.54%	494,278,594	29.25%
Fentanyl	9801	51,159,276	42,971,667	914,488,221	0.65%	8,096,158	0.48%
Hydromorphone	9150	17,446,169	14,435,387	2,571,523,184	1.84%	15,161,478	0.90%
Subtotal		374,628,628	338,447,296	117,750,464,388	84.07%	954,265,749	56.48%
Received July 6, 2018							
Morphine	9300	49,243,546	39,880,848	6,365,919,333	4.55%	222,022,285	13.14%
Buprenorphine	9064	26,275,507	24,153,401	1,857,399,214	1.33%	152,570,080	9.03%
Oxymorphone	9652	6,033,613	5,008,054	633,293,763	0.45%	11,042,968	0.65%
Tapentadol	9780	3,376,288	2,827,854	353,918,908	0.25%	28,776,260	1.70%
Subtotal		84,928,954	71,870,157	9,210,531,218	6.58%	414,411,593	24.53%
Received July 24, 2018							
Codeine	9050	17,644,740	14,728,585	5,904,595,163	4.22%	149,048,894	8.82%
Meperidine	9230	6,069,787	4,439,671	296,424,349	0.21%	25,276,542	1.50%
Dihydrocodeine	9120	1,150,066	762,778	47,182,023	0.03%	1,051,401	0.06%
Opium, Powdered	9639	509,879	335,515	8,000,328	0.01%	383,634	0.02%
Subtotal		25,374,472	20,266,549	6,256,201,863	4.47%	175,760,471	10.40%
Received August 28, 2018							
Methadone	9250	15,668,247	14,167,720	6,829,158,005	4.88%	145,228,224	8.59%
Levorphanol	9220	109,502	67,460	14,402,593	0.01%	18,947	0.00%
Subtotal		15,777,749	14,235,180	6,843,560,598	4.89%	145,247,171	8.60%
Total		500,709,803	444,819,182	140,060,758,067	100.00%	1,689,684,984	100.00%

B. ARCOS Data Fields Produced by DEA

25. The ARCOS Data produced by the DEA has the 34 fields illustrated in Figure 1 for each transaction record. Twelve of the 34 fields are submitted with each transaction record by the Reporting Registrant, the DEA registered entity reporting the opioid shipment through ARCOS. These twelve fields are defined in the ARCOS Handbook.⁵ The remaining 22 fields were appended by the DEA to the transaction records submitted by the Reporting Registrant.⁶ Eighteen of the 22 fields are information about the Reporting Registrant and the Associate Registrant, keyed off their DEA numbers.⁷ Three of the remaining four fields are either taken from the NDC (for National Drug Code) Dictionary or are calculated using variables therein and appear to have been imported by the DEA into the data it produced by matching each transaction's NDC number with the NDC number in the NDC Dictionary.⁸

Figure 1 ARCOS Data Fields Produced by DEA

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Reporter / Seller Info										Buyer Info										Transaction Info													
DEA #	Business Activity	Name	Address1	Address2	City	State	Zip	County		DEA #	Business Activity	Name	Address1	Address2	City	State	Zip	County		Transaction Code	Drug Code	Drug Name	Quantity	Unit	Action Indicator	Order Form Number	Correction Number	Strength	Transaction Date	Calc Base Weight Grams	Dosage Unit	Transaction Id	

⁵ “ARCOS Registrant Handbook,” Drug Enforcement Administration, August 1997 (“ARCOS Handbook”). Current version available at www.deadiversion.usdoj.gov/arcos/handbook/full.pdf.

⁶ The 22 fields are Reporter Business Activity, Reporter Name (2 fields), Reporter Address (6 fields), Buyer Business Activity, Buyer Name (2 fields), and Buyer Address (6 fields), Drug Code, Drug Name, Calculated Base Weight in Grams, and Dosage Unit.

⁷ The 18 fields are Reporter Business Activity, Reporter Name (2 fields), Reporter Address (6 fields), Buyer Business Activity, Buyer Name (2 fields), and Buyer Address (6 fields).

⁸ Drug Code and Drug Name are both in the NDC Dictionary. Calculated Base Weight in Grams is calculated using Ingredient Base Weight in the NDC Dictionary and Quantity, Unit, and Strength in the ARCOS Data.

patients. I call these Buyers “Dispensers.”²⁸ 3.8% of transactions involve shipments from Dispensers back to manufacturers or distributors.²⁹ 5.99% of transactions reported in the ARCOS Data involve shipments to Distributors. The number of transactions from Manufacturers to Distributors is small relative to the number of transactions from Distributors to Distributors but the Dosage Units and Calculated Based Weight in Grams is similar.

57. Table 4 is not entirely informative of the actual flow of opioids because some transactions reported by Reverse Distributors (“from Manufacturers” and “to Analytical Labs”) have incorrect Dosage Units and Calculated Base Weights in Grams. I do not use these Reverse Distributor transactions in the analysis I present below.

58. Only 0.03% of transactions are shipments to or from importers, exporters, or researchers (“Other Buyers”).³⁰

59. I removed seven types of transactions from the ARCOS Data before conducting further analysis:

- Obvious duplicate transactions, when the same transaction was reported to ARCOS more than once by the same registrant.

²⁸ I include the following Buyer Business Activities as Dispensers: any Buyer Business Activity beginning with “MLP”; any Buyer Business Activity containing “PHARMACY”, “PRACTITIONER”, “CLINIC”, “MAINT” or “DETOX”; and “AUTOMATED DISPENSING SYSTEM”, “CANINE HANDLER”, and “TEACHING INSTITUTION.”

²⁹ I include the following Buyer Business Activities as manufacturers or distributors: any Buyer Business Activity containing “MANUF” or “DISTRIB.”

³⁰ Other Buyers have Buyer Business Activity containing “IMPORT”, “EXPORT”, or “RESEARCHER.”

- Transactions where the Drug Code from the NDC Dictionary is not one of the 14 opioids listed in Table 1.
- Transactions where the Action Indicator code, Correction Number, or both suggest the reported transaction is erroneous.
- Transactions involving reverse distributors, analytical labs, importers, exporters, or researchers.
- Transactions reported by the registrant receiving the shipment when two registrants reported the same transaction, keeping the transaction reported by the registrant sending the shipment.
- Transactions with obvious errors in the reported Quantity.
- Transactions where the Transaction Code is “X” (Lost-in-Transit.)

60. I also corrected the Calculated Base Weight In Grams when it was calculated using an incorrect Ingredient Base Weight from the NDC Dictionary. Appendix 2 provides a detailed explanation of these exclusions and corrections.

E. Comparing ARCOS Data to Retail Drug Summary Reports

61. The DEA publishes six ARCOS Retail Drug Summary Reports (“RDSR”) each year, which summarize the weight of opioids reported in ARCOS transactions by various combinations of Drug Code, Calendar Quarter, Buyer State, Buyer Zip Code, or Buyer’s business activity.³¹ The

³¹ The six summary reports are updated on an ad hoc basis. The DEA website states that the summary reports are “susceptible to future updates and corrections, without notice, as new information is obtained”

(www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html).

transaction data. 72.4% of the observations have RDSRs reported summary weights within 1.0% of the weights I aggregate up from the processed ARCOS transaction data.

67. The RDSRs confirm the accuracy of the ARCOS Data I received. The correlation between the RDSRs' reported drug weight and the weights I calculate from the ARCOS Data is **0.999** on a scale from -1.00 to +1.00.

Table 6 Ratios of Retail Drug Summary Report and ARCOS Drug Weights

Drug Code	N	N(%)	1st Percentile	5th Percentile	25th Percentile	50th Percentile	75th Percentile	95th Percentile	99th Percentile
9050	32,155	7.9%	0.97	1.01	1.04	1.07	1.11	1.20	1.32
9064	31,923	7.8%	0.76	0.92	1.00	1.00	1.00	1.02	1.09
9120	23,214	5.7%	0.00	0.71	1.00	1.00	1.00	1.01	1.19
9143	32,119	7.9%	0.90	0.97	1.00	1.00	1.00	1.02	1.11
9150	32,042	7.8%	0.82	0.97	1.00	1.00	1.00	1.03	1.28
9193	32,164	7.9%	0.89	0.98	1.00	1.00	1.00	1.04	1.35
9220L	13,821	3.4%	0.93	0.93	0.99	1.00	1.00	1.03	1.03
9230	32,049	7.8%	0.89	0.98	1.00	1.00	1.01	1.12	1.37
9250B	32,075	7.9%	0.86	0.99	1.00	1.00	1.00	1.02	1.30
9300	32,111	7.9%	0.88	0.98	1.00	1.00	1.00	1.03	1.17
9639	30,138	7.4%	0.91	1.00	1.00	1.00	1.00	1.00	1.06
9652	31,287	7.7%	0.75	0.94	1.00	1.00	1.00	1.00	1.10
9780	21,175	5.2%	0.93	1.00	1.00	1.00	1.00	1.00	1.07
9801	32,116	7.9%	0.84	0.95	0.98	1.00	1.00	1.06	1.31
Total	408,389	100.0%	0.81	0.96	1.00	1.00	1.00	1.09	1.24

F. Shipments to Dispensers in ARCOS Data

68. Table 7 summarizes the shipments to Dispensers in the ARCOS Data, grouped by the Reporter's Business Activity. Distributors account for 98.6% of Dosage Units, 97.9% of Calculated Base Weight in Grams and 97.9% of MME shipped to Dispensers. Manufacturers account for the remaining 1.4% of Dosage Units, 2.1% of Calculated Base Weight in Grams and 2.1% of MME shipped to Dispensers.

Table 18 Oxycodone and Hydrocodone Shipments to Selected Pharmacies in Cabell County and the City of Huntington, WV, by Distributor Market Share, 2006 - 2014

	DU Market Share % ⁹	MME Market Share % ¹⁰	Distributor MME % for the Pharmacy ¹¹					Total DU	Total MME	
			ABDC	MCK	CAH	Self- Distributed	Other			
<i>Selected Independent Pharmacies</i>										
Fruth (4 pharmacies) ¹	18.24%	13.39%	52.73%	0.21%	44.39%	-	2.67%	14,850,710	116,335,714	
SafeScript (1 pharmacy) ²	5.42%	13.30%	85.19%	-	-	-	14.81%	4,414,640	115,590,031	
Medicine Shoppe (2 pharmacies) ³	7.25%	11.99%	9.68%	0.01%	79.49%	-	10.83%	5,900,850	104,202,758	
McCloud (1 pharmacy) ⁴	5.55%	8.20%	99.25%	-	-	-	0.75%	4,519,980	71,248,721	
Drug Emporium (1 pharmacy) ⁵	4.83%	5.72%	99.86%	-	-	-	0.14%	3,928,100	49,723,696	
Selected Independent Totals	41.29%	52.60%	63.50%	0.05%	29.42%	-	7.03%	33,614,280	457,100,919	
<i>Selected National Chain Pharmacies</i>										
CVS (4 pharmacies) ⁶	17.45%	14.36%	-	-	66.86%	33.14%	-	14,204,630	124,758,090	
Rite Aid (5 pharmacies) ⁷	10.81%	8.33%	-	64.36%	-	35.21%	0.42%	8,801,300	72,422,370	
Walgreens (2 pharmacies) ⁸	3.10%	2.90%	35.13%	0.07%	3.31%	61.48%	0.01%	2,522,800	25,216,573	
National Chain Totals	31.36%	25.59%	3.98%	20.97%	37.88%	37.03%	0.14%	25,528,730	222,397,034	
Selected Grand Total	72.65%	78.19%	44.02%	6.90%	32.19%	12.12%	4.77%	59,143,010	679,497,953	

B. Defendants' Shipment Summary

82. In addition to receiving the ARCOS Data produced by the DEA, I received Transactional Data produced in discovery by three Defendants, AmerisourceBergen Drug, Cardinal Health, and McKesson Corporation. I analyzed the Defendants' Transactional Data and found that there are small gaps in the data produced by Defendants. I compared transactions in each Defendant's Transactional Data to the ARCOS Data. I matched the transactions based on NDC, Buyer's DEA Number, Quantity, and the transaction date (within ± 5 days). After matching the transactions, I converted the transaction Quantity to both Dosage Units and MME.

83. Table 19 presents summary statistics comparing the ARCOS Data and the Defendants' Transactional Data. The transactions summarized in Table 19 consist of all transactions by Dispensers in Cabell County and the City of Huntington, WV from January 1, 2006 through December 31, 2014, involving the 14 opioids in Table 12.

Table 19 Overlap between ARCOS Data and Defendant Data

Defendant	Transaction in Both Datasets		Transactions Only in ARCOS				Transactions Only in Defendants			
	Dosage Unit	MME	Dosage Unit	%	MME	%	Dosage Unit	%	MME	%
Cardinal Health	21,900,738	576,084,297	5,933	0.03%	83,633	0.01%	84,431	0.39%	2,264,666	0.39%
AmerisourceBergen Drug	41,539,089	841,218,973	32,135	0.08%	1,024,980	0.12%	27,670	0.07%	369,063	0.04%
McKesson Corporation	30,171,356	601,399,381	3,700	0.01%	28,915	0.00%	67,865	0.22%	957,501	0.16%
Total	93,611,183	2,018,702,651	41,768	0.04%	1,137,527	0.06%	179,966	0.19%	3,591,230	0.18%

84. Using my matching criteria, over 99.8% of all MME or Dosage Units in either the ARCOS Data or the datasets produced by Defendants are in both the ARCOS Data and the datasets produced by Defendants (*i.e.*, the MME and Dosage Units are in the intersection of the ARCOS Data and the datasets produced by Defendants).

85. The 99.8% overlap between the ARCOS Data and the datasets produced by Defendants demonstrates that the ARCOS Data and the datasets produced by Defendants in discovery are both reliable. The remainder of this section explains the slight differences between the ARCOS Data and the Defendants' data.